K 080530

Attachment 10
510(k) Summary for the
Cutera Er:YSGG Laser System

AUG 15 2008

I. General Information

Submitter: Cutera, Inc.
3240 Bayshore Blvd
Brisbane, CA 94005

Contact Person: Kathy Maynor

Telephone: 415-657-5586
Fax: 415-330-2443

Summary Preparation Date: February 23, 2008

II. Names

Device Proprietary Name: Cutera Er:YSGG Laser Handpiece

Classification Name: Instrument, Powered, Laser, GEX

Common Name: Dermatology Laser

III. Predicate Devices

- K063867 Cutera Er:YSGG Laser Hand Piece

IV. Product Description/Technological Characteristics

The Cutera Er:YSGG Laser handpiece is an optional handpiece for the currently marketed Xeo and Solera Opus laser systems. The handpiece emits laser energy at a wavelength of 2790nm. The water cooled laser is located in the handpiece and utilizes a computer controlled scanner.

V. Statement of Intended Use

Cutera Er:YSGG Laser Hand Piece (K063867 – 4-8 mm spot size)

The Cutera Er:YSGG Laser System is designed for use in applications requiring the excision, incision, ablation, vaporization and coagulation of soft tissue. For

Dermatology and Plastic Surgery, indications include: treatment of wrinkles and skin resurfacing. For Opthalmology, indications include: Incision, excision, vaporization and coagulation of tissue surrounding the eye and orbit.

Cutera Er:YSGG Laser Hand Piece (K080530) – Fractionated/Small Spot Size

The Cutera Fractionated Er:YSGG laser hand piece is designed for use in dermatology for skin resurfacing and for coagulation.

VI. Rationale for Substantial Equivalence

The Cutera Er:YSGG Handpiece shares the same general indications for use as the currently marketed predicate devices, and does not raise any issues with safety and effectiveness. The Cutera Er:YSGG Handpiece is therefore substantially equivalent to the currently marketed predicate devices.

VII. Safety and Effectiveness Information

Technologically, the Cutera Er:YSGG Handpiece is substantially equivalent to the listed predicate devices. Therefore the risks and benefits for the Cutera Er:YSGG Handpiece are comparable to the predicate devices.

Cutera therefore believes that there are no new questions of safety or effectiveness raised by the introduction of this device.

VIII. Conclusion

The Cutera Er:YSGG Handpiece was found to be substantially equivalent to currently marketed devices. The Cutera Er:YSGG shares similar indications for use, design features, and similar functional features as the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cutera, Inc.
% Ms. Kathy Maynor
VP of Regulatory/Quality
3240 Bayshore Boulevard
Brisbane, California 94005

AUG 15 2008

Re: K080530
Trade/Device Name: Cutera Er:YSGG Laser Hand Piece
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: July 7, 2008
Received: July 17, 2008

Dear Ms. Maynor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2
Indications For Use Statement

510(k) Number (if Known): K080530

Device Name: **Cutera Er:YSGG Laser Hand Piece**

Indications for Use (K063867) – Er:YSGG Laser Hand Piece - 4-8 mm spot size:
The Cutera Er:YSGG laser hand piece is designed for use in applications requiring the excision, incision, ablation, vaporization and coagulation of soft tissue.

Dermatology and Plastic Surgery
Indications include: treatment of wrinkles and skin resurfacing

Opthalmology
Indications include: Incision, excision, vaporization and coagulation of tissue surrounding the eye and orbit.

Indications for Use (K080530) –Er:YSGG Laser Hand Piece - Fractionated/Small spot size
The Cutera Fractionated Er:YSGG laser hand piece is designed for use in dermatology for skin resurfacing and for coagulation.

Prescription Use √ OR Over-The-Counter Use _____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K080530